

**REMARKS**

Reconsideration of the rejection of elected claim 19 and rejoinder of withdrawn claims 24 and 26 are respectfully requested in view of the above amendments and the following remarks.

***Claim Amendments and Status of the Claims***

Withdrawn claims 24 and 26 have been amended above so as to maintain their eligibility for rejoinder as species upon allowance of elected generic claim 19.

It should be clear from the above that no new matter has been added by the above amendments. These amendments are being made without waiver or prejudice to Applicant's right to prosecute any subject matter thereby deleted in one or more divisional or continuing applications.

Following entry of these amendments, claims 19, 24 and 26 are pending in this application with claims 24 and 26 being designated as "withdrawn."

Pursuant to the restriction requirement, Applicant elected the invention of Group III (claims 19-26 drawn to various method procedures), and pursuant to the Examiner's requirement for election of species, Applicant provisionally elected species (1) a method of preventing or treating atherosclerosis, being claim 19. Upon allowance of the elected generic claim (claim 19), the Examiner noted that Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim. Withdrawn claim 24 (method of treating atherosclerosis ... by inhibition of expression of CD40 and/or metalloproteinases (MPPs)) and withdrawn claim 26 (method of treating atherosclerosis ... by inhibition of expression of LOX-1) appear to be species of elected claim 19, directed toward a "method of treating or reducing the extent of atherosclerosis." Inasmuch as claims 24 and 26 are also directed toward a method of treating atherosclerosis, and by reason of the above amendments they include all the limitations of elected generic claim 19. It seems appropriate claims 24 and 26 be rejoined with method claim 19 for prosecution in the present application, now or at least upon allowance of claim 19.

***Status of Prior Grounds for Rejection***

It is noted with appreciation that the Examiner has withdrawn the previous rejection under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, and has also withdrawn consideration of the Quin *et al.* and

Leyland-Jones references, which had been applied to the obviousness rejection under 35 U.S.C. § 103 in the April 30, 2008 Action. The Examiner states in the third paragraph on page 3 of the Action:

Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

These Remarks therefore will focus entirely on the statement of the obviousness rejection and grounds therefore as set forth beginning in the middle of page 3 of the current Action.<sup>1</sup>

### ***Claim Rejections under 35 U.S.C. § 103***

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robl, US Patent 6,620,821(hereinafter “Robl ‘821”) alone. This ground for rejection is respectfully traversed, in that the Robl disclosure does not meet even the minimum criteria for “obvious to try” under *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 [82 USPQ2d 1385, 1398](2007).

The Court in *KSR* explained that the Federal Circuit's “teaching, suggestion or motivation” test provides helpful insight into the obviousness question as long as it is not applied rigidly and that, accordingly, it remains necessary for the Examiner to *identify some reason* that would have led a chemist to modify the prior art in a particular manner to establish *prima facie* obviousness of the claimed invention. Moreover, “obvious to try” does not arise simply because the components of the claimed invention are separately known in the art, but rather a particular combination might be obvious to try only when “there is a design need or market pressure to solve a problem and there are *a finite number of identified, predictable solutions*, and a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. The Supreme Court's *KSR* reasoning was summarized and applied by the Federal Circuit, for example, in its very recent decision in *Procter & Gamble Co. v. Teva Pharmaceuticals USA Inc.*, 90 USPQ2d 1947, 1949-50 (Fed. Cir. 2009). After noting that the obviousness determination turns on the four underlying *Graham v. John Deere* factual inquiries, the Court continued:

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<sup>1</sup> Accordingly, this response will not specifically address the Examiner's assertions made in the last four paragraphs on page 2 and the first paragraph on page 3 (which the undersigned either disagrees with or does not understand) except to the extent such assertions may be reiterated or newly stated in the current rejection following the above-quoted paragraph.

The Supreme Court has explained that *the Federal Circuit's "teaching, suggestion or motivation" test provides helpful insight into the obviousness question as long as it is not applied rigidly.* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 127 S. Ct. 1727, 1741 [82 USPQ2d 1385] (2007). Accordingly, under KSR, "it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound." Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1357 [83 USPQ2d 1169] (Fed. Cir. 2007).

(90 USPQ2d at 1949-50; emphasis added). The Court continued:

When a person of ordinary skill is faced with "a finite number of identified, predictable solutions" to a problem and pursues "the known options within his or her technical grasp," the resulting discovery "is likely the product not of innovation but of ordinary skill and common sense." *KSR*, 127 S. Ct. at 1742. So too, "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress." *Id.* at 1741. *In other cases*, though, researchers can only "vary all parameters or try each of numerous possible choices until one possibly arrive[s] at a successful result, where the prior art [gives] either no indication of which parameters [are] critical or no direction as to which of many possible choices is likely to be successful." *In re O'Farrell*, 853 F.2d 894, 903 [7 USPQ2d 1673] (Fed. Cir. 1988). In such cases, "courts should not succumb to hindsight claims of obviousness." *In re Kubin*, 561 F.3d 1351, No. 2008-1184, slip op. at 14 [90 USPQ2d 1417] (Fed. Cir. Apr. 3, 2009).

(90 USPQ2d at 1952; emphasis added),

It is respectfully submitted that Robl '821 does not give the skilled person a finite number of identified, predictable solutions to a problem, and certainly gives no guidance or motivation to combine candesartan with rosuvastatin for the treatment of atherosclerosis. To the contrary, the Robl '821 disclosure is focused entirely on Robl's proprietary compound of "structure I," and rosuvastatin and candesartan are simply and *separately* included in an exhaustive recitation of myriads of other diverse types of therapeutic agents that may be used in combination with a compound of Robl's structure I. No particular objective or goal is stated for combining these other therapeutic agents with compounds of structure I. As the Examiner notes, Robl '821 does say that the compounds of structure I may be used in combination with *one or more* of the

thereafter listed other therapeutic agents, but no objective or reason is given as to *why* any *two or more* of such other therapeutic agents should be combined with the compounds of structure I, no less than *both* rosuvastatin *and* candesartan should be selected out of that exhaustive list for combination *together* with compounds of Robl's structure I. Accordingly, even under *KSR* and its "obvious to try" threshold, the Examiner has not made out a case for *prima facie* obviousness of the presently claimed invention, as the Federal Circuit has interpreted and applied *KSR* to pharmaceutical inventions.

#### ***Robl '821 Disclosure vs. Examiner's Characterization Thereof***

The invention of Robl '821 is a new HMG CoA reductase inhibitors most generally referred to and illustrated therein as compounds of "structure I." Compounds of structure I are disclosed in detail in columns 1 through 27 of this reference, and "structure I" clearly does not encompass either rosuvastatin or candesartan. Other aspects of the invention are the administration of compounds of structure I for the treatment of a variety of disease conditions listed, *e.g.*, over columns 5 and 6 of the specification, including "preventing or reversing progression of atherosclerosis" among with myriads of other diverse disease conditions.

Following the 27 columns of description of the compounds of the invention and the disease conditions treated thereby, Robl '821 notes in the middle of column 28 that the "HMG CoA reductase inhibitors of formula I may be employed in combination with *all therapeutic agents* which are useful in combination with HMG CoA reductase inhibitors." However, there is no indication of the objective to be achieved by making such combinations, or even an indication as to why these other therapeutic agents "are useful in combination with HMG-CoA reductase inhibitors." The following paragraph then lists the various *types* of other therapeutic agents with which compounds of the structure I may be combined, including, in the order listed at column 28, lines 33-49:

hypolipidemic agents or  
lipid-lowering agents, or  
lipid agents, or  
lipid modulating agents,

and/or one or more other types of therapeutic agents including

antidiabetic agents,  
anti-obesity agents,  
antihypertensive agents,  
platelet aggregation inhibitors,  
anti-Alzheimer's agents,  
anti-dementia agents,  
anti-osteoporosis agents, and/or  
hormone replacement therapeutic agents, and/or  
other therapeutic agents, and/or  
other cardiovascular agents (including  
anti-anginal agents,  
anti-arrhythmic agents,  
anti-atherosclerosis agents,  
anti-inflammatory agents,  
anti-platelet agents,  
anti-heart failure agents),  
anti-cancer agents,  
anti-infective agents,  
hormone replacement agents,  
growth hormone secretagogues,  
selective androgen receptor modulators,  
and/or other therapeutic agents which may be administered orally in the same dosage form or  
in a separate oral dosage form, or by injection.

The Robl '821 reference then provides, in columns 28 through 39, what virtually amounts to a shopping list of possible combination products within each of the above-listed therapeutic agent types. Amongst this very extensive disclosure of diverse types of other therapeutic agents, there is a discussion of multiple sub-categories of "hypolipidemic agent or lipid-lowering agent or other lipid agent or lipid modulating agent," and an even more extensive listing of various genus and species of compounds within these sub-categories, which are reported from column 28, line 50 through column 31, line 54, including various known HMG-CoA reductase inhibitors

(pravastatin, lovastatin, simvastatin, atorvastatin, fluvastatin, cerivastatin, pitavastatin and rosuvastatin), as well as niacin and/or cholestagel, all of which are indicated as being preferred.

Amongst this very extensive disclosure of diverse types of other therapeutic agents there is also a discussion extending from column 35, line 62 through column 37, line 61 of various types of “antihypertensive agents which may be employed in combination with the HMG CoA reductase inhibitors of the invention,” including ACE inhibitors, angiotensin II receptor antagonists, NEP inhibitors, NEP/ACE inhibitors, calcium channel blockers, T-channel calcium antagonists,  $\beta$ -adrenergic blockers, diuretics,  $\alpha$ -adrenergic blockers, dual action receptor antagonists, heart failure drugs and “other types of antihypertensive agents.”

The angiotensin II receptor antagonists are specifically discussed at column 37, lines 16-20, wherein it is noted that “the angiotensin II receptor antagonist (also referred to herein as angiotensin II antagonist or AII antagonist) suitable for use herein includes, but is not limited to irbesartan, losartan, valsartan, candesartan, tasosartan or eprosartan, with irbesartan, losartan or valsartan being preferred.” This is the *only* mention of candesartan in the *entire Robl '821 disclosure*, as one of six AII antagonists, the AII antagonists being only one of nine or more *types of antihypertensive agents*, the antihypertensive agents being only one of the multitudes of other *types of therapeutic agents* exhaustively listed over 11 columns of the disclosure. No preference is expressed for combination of compounds of Robl's structure I with AII antagonists as opposed to any other of the listed therapeutic agents, and candesartan is not even one of the three preferred AII antagonists, as noted in the above-quoted passage.

Clearly, the separate, unassociated listing of rosuvastatin and candesartan, columns apart in this 12 column exhaustive recitation of myriads of other diverse types of therapeutic agents, one or more of which may be used in combination with the compounds of Robl's structure I, does not constitute “*a finite number* of identified, predictable solutions” required by the Supreme Court in *KSR* to make the combination of candesartan with rosuvastatin “obvious to try” in the treatment of atherosclerosis.

It again should be noted that there is no particular objective or goal stated in Robl '821 for combining these other therapeutic agents with compounds of Robl's structure I. In particular, there is no suggestion that these other therapeutic agents will work effectively in combination with compounds of Robl's structure I purpose of treating atherosclerosis (except perhaps those

specific agents that are defined or otherwise characterized in the listing as anti-atherosclerosis agents). Rather, the only selection criteria even suggested for this massive listing of other therapeutic agents is that they are “all therapeutic agents which are useful in combination with combination with HMG CoA reductase inhibitors (col. 28, lines 28-31), without indication or statement as to *why* they may be useful in combination with HMG CoA reductase inhibitors. Therefore, there also is no “*design need or market pressure to solve a problem*” with a finite number of identified, predictable solutions, as is also required by *KSR* for this reference to make a combination of candesartan with rosuvastatin “obvious to try.”

Several comments and clarifications with respect to the Examiner’s current characterization of the Robl ’821 disclosure are believed to be in order. Paragraphs from the Action will be reproduced exactly as they appear in the Action so there can be no mischaracterization of sometimes ambiguous statements:

At page 4 of the Action the Examiner paraphrases a portion of the Robl Abstract as follows:

Robl teaches compounds of the following structure are HMG CoA reductase inhibitors and thus are active in inhibiting cholesterol biosynthesis, modulating blood serum lipids, for example, lowering LDL cholesterol and/or increasing HDL cholesterol, and **treating** hyperlipidemia, dyslipidemia, hormone replacement therapy, hypercholesterolemia, hypertriglyceridemia and **atherosclerosis** as well as Alzheimer’s disease and osteoporosis.

It is presumed that the Examiner understands that the “following structure” referred to in the Abstract is Robl’s structure I, which does not encompass either rosuvastatin or candesartan. Moreover, the Abstract is referring *only* to compounds of Robl’s structure I with respect to this treatment, and is not including any of the multitudes of other therapeutic agents that the specification later states “may be used in combination with” compounds of structure I.

The Examiner continues at page 4 of the Action:

With regard to an **effective amount of a combination comprising**, Robl teaches [a] preferred oral dosage form, such as tablets or capsules, will contain the ACE inhibitor or All antagonist in an amount within the range from about 0.1 to about 500 mg, preferably from about 5 to about 200 mg and more preferably from

about 10 to about 150 mg. Both candesartan and rosuvastatin taught in a combination formulation as disclosed above would preferably be in an amount of between [sentence incomplete in original]

The oral dosage form information for the ACE inhibitor or AII antagonist is found in Robl '821 at column 37, lines 21-25, in the middle of the extensive listing of antihypertensive agents that may be combined with Robl's compounds of structure I. Although not mentioned by the Examiner, the preferred oral dosage form for the HMG CoA reductase inhibitor that may be combined with Robl's structure I (being from about 0.1 to about 100 mg, preferably from about 0.5 to about 80 mg, and more preferably from about 1 to about 40 mg) is found in Robl '821 at column 32, lines 30-34, at the end of the extensive listing of hypolipidemic agents that may be combined with Robl's compounds of structure I.

It is presumed that the Examiner's bolded reference to "**an effective amount of a combination comprising**" is reference to Applicant's claim 19, quoted earlier on page 4 of the Action. However, the beginning of the Examiner's partial sentence, "[b]oth candesartan and rosuvastatin taught in a combination formulation as disclosed above would preferable be in an amount of between [sentence ends here]" is *clearly wrong*. There is no "combination formulation" of candesartan and rosuvastatin disclosed, no less suggested, *anywhere* in Robl '821.

At the top of page 5 of the Action, the Examiner quotes three paragraphs from present Applicant's specification with regard to "suitable dosages" of Applicant's claimed combination of candesartan and rosuvastatin, specifically stating that "suitable dosage of each component of the combination are those of the marketed commercial products," or may be lower dosage of one or both components due to the "synergy between the components." It is therefore not surprising that these suitable dosages fall within the very broad range of dosages disclosed in Robl '821 for known HMG CoA reductase inhibitors at column 32, and for known ACE inhibitors or AII antagonists in column 37.

The Examiner then states at page 5:

Robl teaches candesartan (col. 37, line 19).

Robl teaches rosuvastatin (col. 28, line 21).<sup>2</sup>

Robl teaches the embodiments drawn to combination therapy in the treatment of atherosclerosis.

The “embodiments” the Examiner refers to are the many *types* of therapeutic agents listed by Robl that may be used in combination with compounds of Robl’s structure I, which Robl then expands over columns 28 through 39 into the listing of myriads of known therapeutic compounds, as discussed above in this response beginning at the bottom of page 6. The Examiner correctly observes at the bottom of page 6 that “candesartan is not taught in any direct combination with rosuvastatin” in Robl.

Robl itself does no more than separately include candesartan and rosuvastatin in an enormous, all-encompassing list of known therapeutic agents, one or more of which may be combined with a compound of Robl’s structure I. There is no objective stated in Robl ‘821 for making any of the tens or hundreds of thousands of combinations that conceivably could be made from various selections of “one or more” of any of these listed therapeutic agents with one another (and structure I), *except that “they may be used in combination”* (col. 28, lines 32-33). While the Examiner selects the treatment of atherosclerosis from the many indications that Robl lists as potentially treatable by compounds of Robl’s structure I, there is no teaching in Robl ‘821 that any of the other therapeutic agents will (other than perhaps those specifically identified as “anti-atherosclerosis agents” at, *e.g.*, column 7, lines 55-59) will enhance the effectiveness of compounds of structure I *in the treatment of atherosclerosis*, as opposed to accomplishing some entirely different function (*e.g.*, treat Alzheimer’s disease or provide hormone replacement therapy; *see, e.g.*, column 28, lines 39-40).

In short, the mention of candesartan and the mention of rosuvastatin in Robl’s 12-column listing of other therapeutic agents that may be combined with a compound of structure I, are so separate and unrelated that there is *no way* that the skilled person would be led to select *both*

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<sup>2</sup> For accuracy, it should be noted that the reference to rosuvastatin at column 28, line 21 of Robl ‘821 is in context of “compounds of the present invention *can be administered in a similar manner as known compounds* suggested for use in inhibiting cholesterol biosyntheses ...” *emphasis added*). However, rosuvastatin is listed, *e.g.*, at column 29, line 40, as one of the myriads of known therapeutic agents that may be used in combination with compounds of Robl’s structure I.

candesartan and rosuvastatin for simultaneous combination with compounds of structure I. Moreover, and with all due respect, it seems inconceivable that a *skilled* person in this art would consult *Robl '821* for information on the treatment of atherosclerosis (being only one indication out of Robl's lengthy recitation of indications), and then specifically select candesartan to combine with rosuvastatin from the tens or hundreds of thousands of possible combinations of "one or more" of the listed therapeutic agents that may be combined with a compound of Robl's structure I. The Examiner has not pointed to any guidance in Robl that would lead the skilled person to make these specific multiple selections needed to make the presently claimed combination -- only the impermissible use of hindsight from Applicant's present disclosure.

Although *KSR* may be considered to have eased an examiner's burden of proof to make a case of *prima facie* obviousness, it is respectfully submitted that the present Examiner's rejection based on *Robl '821 per se* falls well short of the threshold level of proof maintained by the Supreme Court. This clearly is not a case where a person of ordinary skill is faced with "a *finite* number of identified, predictable solutions" *KSR*, 127 S. Ct. at 1742. Rather, this is clearly one of the "other cases" where researchers can only "vary all parameters or *try each of numerous possible choices* until one possibly arrive[s] at a successful result, where the prior art [gives] either no indication of which parameters [are] critical or *no direction as to which of many possible choices is likely to be successful.*" In such cases, the "*courts should not succumb to hindsight claims of obviousness.*" *Procter & Gamble Co. v. Teva Pharmaceuticals, quoted supra.*

It is therefore respectfully submitted that this sole remaining ground for rejection, based only on *Robl '821 per se*, does not establish *prima facie* obviousness of Applicant's claimed invention, and that this rejection therefore should be withdrawn.

#### ***Update on Applicant's PCT and Corresponding European Application***

At page 10 of Applicant's October 30, 2008 Amendment and Response, Applicant attached and called the Examiner's attention to the Written Opinion of the International Searching Authority, which issued in the PCT application of which the present application is the US National Stage. It was pointed out that each reference discussed in the Written Opinion was cited in the International Search Report, and that a copy of the International Search Report and each of the cited references had previously been cited and submitted in the present application.

It was further called to the Examiner's attention that documents D3 (EP1314425), D4 (WO95/26188) and D5 (JP 200214577; abstract) were specifically discussed in the Written Opinion, which concluded that the subject-matter of claims 1 to 11 seems to be novel and to involve an inventive step, and that documents D1 (Chen et al.) and D2 (WO2004/96810) were not considered to constitute prior art inasmuch as their prior art effective dates are later than the September 26, 2003 priority date to which the present application is entitled. The present Examiner had already considered each of these references in the present application, as acknowledged by the initialed copy of the forms PTO-1449 filed March 24, 2006 and June 22, 2006, returned with the US PTO paper mailed June 11, 2008.

Applicant wishes to call the Examiner's attention to the fact that the corresponding European Application EP04768663 has been allowed and grant is now currently pending. A copy of the file history of this corresponding European Application is attached for the record.

The Examiner's attention is called, in particular, to the Communication pursuant to Article 94(3) EPC dated December 13, 2007 (hereinafter "Examination Report") wherein the claims were found to have novelty and inventive step over the applied prior art, leaving only formal grounds for correction.

The Examination Report considered documents D1 to D8 as follows:

- D1:** **Chen Jiawei et al.** (Journal Of The American College Of Cardiology, vol. 43, no. 5 Supplement A, 3 March 2004, page 498A)
- D2:** **WO 2004/096810 A** (Pfizer Limited; 11 November 2004)
- D3:** **EP-A-1 314 425** (Sankyo Company, Limited; 28 May 2003)
- D4:** **WO 95/26188 A** (Merck & Co., Inc; 5 October 1995)
- D5:** **Abstracts of JP 2002 145770 A** (Sankyo Co Ltd; 22 May 2002)
- D6:** **WO0045818** (AstraZeneca UK Ltd; 10 August 2000)
- D7:** **WO0176573** (Novartis AG; 18 October 2001)
- D8:** **WO02058731** (Schering Corp.; 1 August 2002).

All of documents D1 to D8 have been previously cited in the present application and acknowledged as having been considered by the Examiner.<sup>3</sup> Documents D1 to D5 were cited in the PCT International Search Report and considered in the Written Opinion discussed in

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<sup>3</sup> Documents D1 – D7 were cited in Applicant's Information Disclosure Statement filed herein on October 3, 2006, and Document D8 was cited in Applicant's Information Disclosure Statement filed herein on June 8, 2007.

Applicants previous October 30, 2008 response. The Examination Report of December 13, 2007 additionally considered documents D6-D8, which were cited by the examining division.

At page 2 of the Examination Report (as with the Written Opinion previously discussed), documents D1 and D2 were not considered inasmuch as they were published after the September 26, 2003 priority date of the present application.

At pages 2-3 of the Examination Report under NOVELTY, each of documents D3 to D8 are discussed with respect to novelty of the claims. Each of the “second medical use”, *i.e.*, treatment claims, was found to be novel, inasmuch as none of these references disclosed a combination of rosuvastatin and candesartan for the treatment of atherosclerosis.

At pages 3-4 under INVENTIVE STEP, the Examination Report states:

In as far as the claimed subject matter is new the following observations as to the requirement of inventive step apply:  
D3 and D7 which are the closest prior art differ from the present invention only in that they do not suggest the claimed combination as such. They give a list of HMG-CoA reductase inhibitors and a list of angiotensin II receptor antagonists.  
The problem to be solved can be described as how to provide further medicaments for the treatment of atherosclerosis.  
None of the prior art documents explicitly suggests the claimed combinations. Moreover, the applicant has shown an synergistic effect of the combination of candesartan and rosuvastatin (see Fig. and pages 10, 11). Therefore, the use of the claimed combinations for the treatment of atherosclerosis seems to be inventive (Article 56 EPC).

All remaining grounds for rejection were overcome by Applicant’s amendments filed in the European Application on March 6, 2008. As a result, corresponding European Application EP04768663 has been allowed and grant is now currently pending.

#### ***Related Copending Application and Information Disclosure Statement***

The Examiner’s attention is called to the further Information Disclosure Statement submitted herewith on which is listed the file history of the corresponding European Patent Application EP04768663 discussed above and also US Published Application 20090186908, published July 23, 2009 in co-pending application 12/222,534 filed August 11, 2008 (of present Applicant’s Assignee), which is a continuation of application 10/935,747 filed September 8, 2004 (now abandoned), which was a continuation of application 09/889,409 filed February 22,

2002 (now US Patent 6,894,058 issued May 17, 2005), which was the US National Stage application of PCT/GB00/00280 filed February 1, 2000, which published as WO 00/45818 on August 10, 2000. Copending application 12/222/534 is presently pending before Examiner Weddington in Group Art Unit 1614, with a first Action presently predicted to be within 21 months.

- WO00/45818 is document D6 discussed in the Examination Report of December 13, 2007 noted above, and it was previously cited herein and a copy provided with the Information Disclosure Statement filed herein on June 8, 2007.
- US Patent 6,894,058 was previously cited herein and a copy provided with the Information Disclosure Statement filed herein on June 8, 2007.
- US Published Application 20090186908, published July 23, 2009, is formally cited on the form PTO-1449 accompanying the further Information Disclosure Statement being submitted herewith.

It is respectfully requested that the Examiner consider the documents cited on the form PTO-1449 accompanying this further Information Disclosure, and acknowledge such consideration by initialing where provided and returning an initialed copy to the undersigned.

### ***Conclusion***

All grounds for rejection have been addressed and, it is believed, overcome by the foregoing remarks. It is therefore respectfully requested that elected claim 19 be allowed, and that related withdrawn claims 24 and 26 be rejoined and allowed in this application.

**EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit

Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully Submitted,  
**Morgan Lewis & Bockius LLP**

Date: **August 27, 2009**  
Morgan Lewis & Bockius LLP  
Customer No. **09629**  
1111 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
Tel. No.: 202-739-3000  
DJB:

By: /Donald Bird/  
Donald J. Bird  
Registration No. 25,323  
Tel. No.: (202) 739-5320  
Fax No.: (202) 739-3001